

Pooled Relative Risk for at least one relapse in four trials including all doses was 0.7, a non-significant RR (95% CI: 0.42–1.17,  $P = 0.17$ ). Summary RR for at least one relapse in two trials in which doses of 3 mg/kg or 6 mg/kg or 300 mg every 4 weeks were administered gave a values of 0.5 as a significant RR (95% CI: 0.42–0.61,  $P < 0.0001$ ). The summary RR for at least one new Gd-enhancing lesion was 0.22, a non-significant RR (95% CI: 0.05–1.01,  $P = 0.051$ ). Three deaths were reported in natalizumab group. Comparing adverse events between natalizumab and placebo yielded a non significant RR of 0.99 (95% CI: 0.96–1.01,  $P = 0.34$ ) for any adverse events ( $n = 3$ ), and a significant RR of 0.39 (95% CI: 0.29–0.52,  $P < 0.0001$ ) for serious adverse events ( $n = 2$ ). A summary RR for withdrawal due to adverse events by natalizumab vs. placebo therapy between two trials was 1.43, a non-significant RR (95% CI: 0.68–3.02,  $P = 0.35$ ). **CONCLUSIONS:** It seems that using 3 mg/kg or 6 mg/kg every four weeks is the best experienced method of administration of natalizumab for preventing relapse and occurrence of new Gd-enhancing. Further clinical trials are still needed.

**PND4****THE FEATURES OF MULTIPLE SCLEROSIS IN IRAN**

**Khanizadeh H<sup>1</sup>, Izham M<sup>2</sup>, Shafie AA<sup>2</sup>, Nikkha K<sup>3</sup>**

<sup>1</sup>University Sains Malaysia(USM), Penang, Malaysia, <sup>2</sup>University Sains Malaysia, Penang, Malaysia, <sup>3</sup>Mashhad University of Medical Sciences, Mashhad, Iran

**OBJECTIVES:** Multiple Sclerosis (MS) is a chronic, recurrent, inflammatory disease with unrelenting attacks from the immune system. It is the major cause of non-traumatic disability in young adults. Iran, contrary to the other countries in Middle-east, is considered to have a high prevalence of MS that mentioned as the National disaster in Iran. While much is known about the MS in the world, there is a paucity of the feature of MS in Iran. **METHODS:** In a 6-month cross-sectional study 248 MS patients were studied in Iran. Data was collected by employing a 32- item self-administered questionnaire. Parametric, nonparametric tests and descriptive statistics analysis were applied ( $p$  value  $< 0.05$ ). **RESULTS:** The prevalence and incidence was estimated to be 25/100000 and 2.5/100,000, respectively. The patients were diagnosed in 2001 onward were more frequently than the patients in 1981–1990(40:1). The mean age  $31.9 \pm 8.7$ , the mean onset age  $26.3(26.3 \pm 8.1)$  and the mean duration of illness were  $5.6 \pm 5.3$  years. A family history of ms was reported in 11%. The sex ratio was 3:1(female:male). **CONCLUSIONS:** In contrast to reports from Caucasians, MS Iranian population significantly differ with respect to the age, onset age, disease duration, family history and sex ratio. This might reflect the different in some environmental-genetic factors and life style as well, in this population. Some of our finding were comparable to the so-called “western type” of MS such as: BMI, birth season and education stand.

**NEUROLOGICAL DISORDERS – Cost Studies****PND5****BUDGET IMPACT ANALYSIS IN THE TREATMENT OF MAJOR DEPRESSIVE DISORDER IN VARIOUS ITALIAN REGIONS: THE ROLE OF VENLAFAXINE**

**Di Matteo S<sup>1</sup>, Colombo GL<sup>2</sup>**

<sup>1</sup>S.A.V.E. Studi Analisi Valutazioni Economiche, Milan, Italy, <sup>2</sup>S.A.V.E. Studi Analisi Valutazioni Economiche, Milano, Milano, Italy

**OBJECTIVES:** Venlafaxine is a serotonin-norepinephrine reuptake inhibitor (SNRI) approved for the treatment of major depressive disorder (MDD). Following patent expiration, venlafaxine is available as generic at a reduced price. We evaluated the overall savings to the National Health System (NHS) following venlafaxine's price reduction. **METHODS:** A simulation model was constructed in Microsoft Excel to carry out a Budget Impact Analysis. Three scenarios were hypothesized: the first simulation evaluated the potential savings to the NHS following venlafaxine's price reduction. The second and third simulations assessed additional potential savings to the NHS supposing an increase in the market share of venlafaxine by substitution of different proportions of other branded products namely duloxetine and escitalopram. Costs were obtained from IMS Health, efficacy data were derived from the available literature. **RESULTS:** Mean annual treatment cost with venlafaxine decreased from €567 to €284 resulting in overall savings to the NHS of more than €44 million per year. Treatment switching from escitalopram and/or duloxetine to venlafaxine was always a dominant strategy and resulted in a higher number of patients treated more efficaciously since venlafaxine performs better in terms of remission and is less expensive. Sensitivity analyses on effectiveness (response) and cost variables confirmed our results. **CONCLUSIONS:** This analysis suggests that extended use of generic venlafaxine is likely to lead to overall cost savings to the NHS due to its cost-effectiveness profile compared with other antidepressants such as duloxetine and escitalopram.

**PND6****ESTIMATION OF PER-MEMBER-PER-YEAR COSTS FOR MANAGING FALLS OR FRACTURES AMONG HYPNOTIC USERS IN A MANAGED CARE PLAN**

**Koerber C<sup>1</sup>, Joish VN<sup>2</sup>, Camacho F<sup>3</sup>, Balkrishnan R<sup>4</sup>, Zammit G<sup>5</sup>**

<sup>1</sup>VE, Marseille, Paca, France, <sup>2</sup>Sanofi-aventis, Bridgewater, NJ, USA, <sup>3</sup>Penn State College of Medicine, Hershey, PA, USA, <sup>4</sup>Ohio State University College of Pharmacy, Columbus, OH, USA, <sup>5</sup>Columbia University College of Physicians & Surgeons, New York, NY, USA

**OBJECTIVES:** Previous research identified hypnotic-users to have a greater risk of falls and fractures vs. controls. The objective of this study was to determine the

economic burden of falls and fractures to managed care among hypnotic users. **METHODS:** A retrospective study was designed using data from a national managed care commercial claims database. First time hypnotic-users were identified using pharmacy claims and matched to two controls on gender, region, payer, and age. Subjects were followed for 12-months post index-date to capture events and costs of falls and fractures identified using specific ICD-9-CM and E-codes. Multivariate regression models were used to estimate the incremental burden of falls or fractures at a per-hypnotic user per year (PHUPY) for a hypothetical managed care plan of 1 million membership with hypnotic-use rate of 4.5% and stratified by age-categories: young-adults (18–44 yrs), middle-age (45–64 yrs) and elderly (>65 yrs). **RESULTS:** A total of 40,549 hypnotic-users and 81,098 controls met the inclusion criteria. Both groups were demographically similar ( $p > 0.05$ ) at baseline. Hypnotic-users had higher Charlson comorbid index scores (1.07 vs. 0.60,  $p < 0.001$ ) and proportion of balance disorders (3.33% vs. 2.18%,  $p < 0.001$ ) compared to controls. For those who had an event, the total annual mean direct costs of managing falls and fractures was \$2,559 (95%CI: 2117–3001), and \$3294 (95%CI: 2916–3673), respectively, with costs linearly increasing with age. Based on hypnotic-use rate of 4.5% and age distribution, total hypnotic-users in the hypothetical plan were estimated to be 33,750. Falls/fracture related PHUPY translated into \$50 (Range: 24–82), \$63 (Range: 39–92), and \$245 (Range: 28–615) for young, middle-age and elderly hypnotic users. Overall burden due to falls/fractures as a consequence of hypnotic use to managed care was estimated to be \$2,092,500 (Range: 1,451,250–2,801,250). **CONCLUSIONS:** The unintended consequence (i.e. managing falls/fractures) of current hypnotic use may be burdensome to a managed care plan.

**PND7****BUDGET IMPACT AND COST—EFFECTIVENESS OF SUGAMMADEX IN THE REVERSAL OF PATIENTS WITH NEUROMUSCULAR BLOCK**

**Subater E<sup>1</sup>, Aguilera L<sup>2</sup>, Canet J<sup>3</sup>, Echevarria M<sup>4</sup>, Lora-Tamayo JI<sup>5</sup>, Poveda JL<sup>6</sup>, Sabaté A<sup>7</sup>, López-Belmonte JL<sup>8</sup>**

<sup>1</sup>Schering-Plough S.A, Alcobendas, Spain, <sup>2</sup>Hospital de Basurto, Bilbao, País Vasc, Spain, <sup>3</sup>Hospital Germans Trias i Pujol, Badalona, Barcelona, Spain, <sup>4</sup>Hospital Nuestra Señora de Valme, Sevilla, Andalucía, Spain, <sup>5</sup>Hospital Infanta Sofía, San Sebastian de los Reyes, Madrid, Spain, <sup>6</sup>Hospital Universitario La Fe, Valencia, Spain, <sup>7</sup>Hospital de Bellvitge, Hospitalet de Llobregat, Barcelona, Spain, <sup>8</sup>Schering Plough S.A, Alcobendas, Madrid, Spain

**OBJECTIVES:** Sugammadex (SGX) is a modified gamma-cyclodextrin that bonds with rocuronium and vecuronium, leading to reversal of the neuromuscular blockade. The objective of this study was to evaluate the budget impact and the cost-effectiveness of SGX in the routine reversal of patients with neuromuscular block (NMB) from the Spanish National Health System perspective. **METHODS:** A decision-analytic (DAM) and a budget impact model (BIM) was developed to assess the mean treatment costs per patient (€2009), life-years gained (LYG), and incremental cost per LYG of SGX, the spontaneous reversal and neostigmine/atropine in the reversal of patients with NMB. The DAM simulates the probability of experiencing an adverse effect and the direct costs produced by each treatment alternative. The BIM accounts for the time that SGX could save in the operating room (OR), shortening the time to extubation, thereby accelerating the movement of patients in and out of the OR. Clinical data was obtained from the clinical trial performed with SGX, the SmPC of each drug and form secondary sources. Costs were obtained for Soikos database. **RESULTS:** In the routine reversal of patients, ROC+SGX is associated with higher costs than the spontaneous reversal or neostigmine/atropine but also with higher LYG. The cost-effectiveness range of SGX vs. neostigmine/atropine varies between €13,26 and 4,976 per LYG, and vs. spontaneous reversal between €6,880 and 17,657 per LYG. In the BIM, SGX could save between 108 and 171 minutes of OR, that would mean that 1 or 2 more surgeries could be performed, and a total budget saved between €1400 and 2000 per OR per day. **CONCLUSIONS:** Under the established assumptions, SGX would be a cost-effective alternative for the routine reversal of patients with NMB and could be a cost-saving strategy due to the increase of the turn over of the OR.

**PND8****COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF SUBCUTANEOUS INTERFERON BETA-1A FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS IN SPAIN**

**Espallardo O<sup>1</sup>, Crespo C<sup>2</sup>, Polanco C<sup>1</sup>, Nieves D<sup>2</sup>**

<sup>1</sup>Merck Serono, Madrid, Spain, <sup>2</sup>Oblikue Consulting, Barcelona, Spain

**OBJECTIVES:** Relapsing-remitting multiple sclerosis (RRMS) is the most common form of multiple sclerosis. Beta interferons have been shown to reduce relapse rates by a third. The aim of this study is assessing the value of subcutaneous interferon beta-1a when compared to other available disease modifying drugs for RRMS patients in Spain. **METHODS:** Pharmacoeconomic model based on subcutaneous interferon beta-1a clinical trials efficacy data (relapses and progression of disability both on the medium and long run) and local expert panel. This analysis was undergone from the Spanish National Health System (SNHS) perspective, included only direct medical costs and employed an annual discount rate of 3% on both costs and health outcomes. The model provided estimations of cost per avoided relapse and cost per avoided progression, as well as probabilistic sensitivity analysis with 1000 Monte Carlo simulations. Budget impact analysis was also undergone to forecast the implications of subcutaneous interferon beta-1a increased market share in a 4-year horizon. **RESULTS:** Subcutaneous interferon beta-1a and natalizumab result in the lowest MS relapse rates with an estimated cost per avoided relapse of €28,847, €29,918, €36,299, €42,027 and €55,379 when subcutaneous interferon beta-1a, interferon beta-1b, glatiramer acetate, natalizumab and intramuscular interferon-1a are employed. Cost per avoided